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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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BAKER BOTTS L.L.P. 2001 ROSS AVENUE SUITE 600 DALLAS, TX 75201-2980			KOROMA, BARBA M	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/751,550	Applicant(s) DAMAJ ET AL.	
	Examiner Barba M. Koroma	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 6-10 and 12-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/1/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, and 17, drawn to an isolated nucleic acid comprising a promoter, an expression vector, a bacterial cell, classified in Class 536, Subclass 23.6, for example.
- II. Claims 7-16 and 18-25, drawn to a method for directing stem-specific expression of a nucleic acid having a JAS promoter, transforming an embryonic callus, and breeding progeny of transformed plant, classified in Class 800, Subclass 278, for example.
- III. Claims 26-33, drawn to a method of directing stem-specific expression of a nucleic acid having an OMT promoter, classified in Class 530, Subclass 300, for example.
- IV. Claims 34-36, drawn to a method of isolating a tissue-specific promoter by adopting microarray and cDNA library techniques, classified in Class 435, Subclass 91.5, for example.

2. The inventions are distinct each from the other because:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as

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claimed can be practiced with another materially different product or, (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acid can be used as a template for *in vitro* transcription and translation.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or, (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the nucleic acid can be used as a template for *in vitro* transcription and translation

Inventions I and IV are unrelated product and process. The nucleic acid of Group I can be used to make a nucleic acid probe, and the method of isolating a tissue-specific promoter by using a microarray can be used isolate different genes encoding different products. Further, a search for both groups would impose a serious search burden since the searches of the different products are not coextensive, as they require distinct steps to be performed. Search of each of these inventions would require different key words and different databases, followed by subsequent in-depth analysis of distinct literature. This would place a serious burden on the Office in terms of both search and examination of the prior art literature. As such, it would be burdensome to perform a search and examination of the different inventions together.

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Inventions II and III are related as patentably distinct methods. Both methods are drawn to different nucleic acid promoters, JAS and OMT. Each promoter has a distinct structure (sequence), function, sets of conditions under which it is inducible.

Inventions of Groups II and IV are patentably distinct. The method of directing a stem-specific promoter function is different from a method of using a micro-array method to isolate a promoter sequence. The method of isolating a promoter using a micro-array can be used to identify patentably distinct nucleic acid products. Furthermore, a search for the claims of both groups together would impose a serious search burden since the prior art searches of the different products are not coextensive, requiring distinct steps, and keywords, followed by subsequent in-depth analysis of distinct and unrelated prior art literature. This would place a serious burden on the Office in terms of search and examination of the prior art literature.

Inventions of Groups III and IV are patentably distinct. The method of directing a stem-specific promoter function is different from a method of using a micro-array method to isolate a promoter sequence. The method of isolating a promoter using a micro-array can be used to identify patentably distinct nucleic acid products. Furthermore, a search for the claims of both groups together would impose a serious search burden on the Office in terms of search and examination of the prior art literature.

3. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art because of their recognized divergent subject matter, and because the search

required for one Group may not reveal information on the other groups, restriction for examination purposes as indicated is proper.

See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
6. During a telephone conversation with Attorney Michel LeCointe on May 5, 2005, a provisional election was made without traverse to prosecute the invention of Group I, SEQ ID No. 1, claims 1-6, and 17. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-16, and 18-36, are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
7. Claims 1-6, and 17 have been examined in this Office action.

Claim Objections

8. Claim 4 is objected for improper use of the word "present" in line 3. Correction is requested.
9. Claim 5 is objected for repeating "in a in a" in line 1. Correction is requested.

Claim Rejections - 35 USC 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which were not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is lack of written description by the specification regarding sequences having at least 65% homology with SEQ ID No. 1, wherein the promoter has stem-specific activity.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

See also MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that:

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a

functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

The claims are broadly drawn to an isolated nucleic acid sequences having at least 65% homology with SEQ ID No. 1, wherein the promoter has stem-specific promoter activity.

The specification describes identification of stem-specific cDNAs (example 1), isolation and cloning of genomic sequence corresponding to JAS gene and promoter release, the JAS promoter was identified to be a 2.686kb fragment, SEQ ID No. 1 (example 3, especially page 40, lines 26-28), vector construction and expression in plants (examples 4).

However, the specification does not describe any and all promoter sequences having at least 65% sequence identity with SEQ ID No. 1, wherein the promoter has stem-specific promoter activity.

The specification fails to provide an adequate written description of the genus of nucleic acids as broadly claimed. Given the lack of written description of the claimed genus of nucleic acids and the claimed expression vector and bacterial cell, are likewise not described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing.

4. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleic acid of SEQ ID No. 1, a promoter with stem specific promoter activity, does not reasonably provide enablement for any nucleic acid promoter sequence that is

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less than 100% and at least 65% identical with SEQ ID No. 1, having stem-specific promoter-activity, as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the Wands factors. In re Wands, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). In re Wands lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. The factors to be considered are as follows: lack of guidance, state of the prior art, nature of the invention, unpredictability of the art, and quantity of experimentation necessary.

Breadth of the claims: The claims are broadly drawn to any nucleic acid that is at least 65% homologous or identical (both terms are synonymous, see page 15, lines 16-24) to SEQ ID No. 1, having stem-specific promoter activity, a JAS promoter operably-linked to a stem-specific exogenous nucleic acid, expression vector, and bacterial cell.

Guidance of the specification: The specification teaches identification of stem-specific cDNAs (example 1), isolation and cloning of genomic sequence corresponding to JAS gene and promoter release, the JAS promoter was identified to be a 2.686kb fragment, SEQ ID No. 1 (example 3, especially page 40, lines 26-28), vector construction and expression in plants (examples 4).

The specification does not teach cloning of any and all any promoter sequences having at least 65% sequence identity with SEQ ID No. 1, wherein the promoter has stem-specific

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promoter activity, having stem-specific promoter activity, a JAS promoter operably-linked to a stem-specific exogenous nucleic acid, expression vector, and bacterial cell.

State of the prior art: Nucleic acid sequences that are least 65% identical SEQ ID No. 1, that have stem-specific promoter, is not taught in the prior art.

Nature of the invention: One skilled in the art would not know how to make and use the multitudes of nucleic acid sequences that are at least 65% identical to SEQ ID No. 1, having stem-specific promoter activity.

Unpredictability of the art: Guidance for making and using the claimed invention is necessary for enablement because of the teaching of Kim et al (Plant Mol Biol. 1994. Vol. 24, pages 105-117) that a twenty-nucleotide sequence region is essential for *nos* promoter function (Abstract; results: page 109, right column, 2nd paragraph). Also, Bilodeau et al (Plant Cell Reports. 1994. Vol. 14, pages 125-130) teach that an almost five-fold increase in gene expression is obtained when the promoter length is increased, and that another ten-fold increase occurs when specific promoter segments are added (Abstract; materials and methods; results and discussion).

Quantity of experimentation necessary: Undue trial and error experimentation would be required to isolate and screen through thousands of promoter fragments that are at least 65% identical to SEQ ID No. 1, make expression constructs, and transform plants to identify those that have stem-specific promoter activity.

Given the breadth of the claims encompassing any and all nucleic acid sequences having at least 65% identity with SEQ ID No. 1, having stem-specific promoter activity, the lack of guidance of the specification as discussed above, it would require undue experimentation to

make and use the invention as claimed. See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-5 and 17, are rejected under 35 U.S.C. 102(b) as being anticipated by Potier et al (WO 0118211 A1. September 1, 2000).

The claims are broadly drawn to an isolated nucleic acid sequence comprising a stem-specific JAS promoter upregulated in the presence of a defense-inducing agent.

The specification defines JAS promoters as stem-specific promoters which drive the expression of jasmonate-induced protein (JAS), and or promoters which are operable primarily in the stem in response to defense-inducing agents (page 6, lines 1-4 and lines 17-19). Potier et al teach all the elements of the claims; stem-specific promoter sequences responsive to defense-inducing agents; exogenous nucleic acids, vectors, and bacterial cells transformed therewith (Abstract, page 1, 2-4 paragraphs; page 8, 2nd paragraph; figures 14-31).

Conclusion

7. No claims are found allowable. Claims 1, 2, and SEQ ID No. 1, are deemed free of the prior art, since the prior does not teach or fairly suggest a stem-specific JAS promoter having the sequence of SEQ ID No. 1.

Contact Information

5. Any inquiry concerning this or earlier communications from the Examiner should be directed to Barba M. Koroma, whose telephone number is 571-272-0899. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 571 273 8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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